UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,669	03/17/2004	Wei-Wu He	PF140P1D2	4076

22195 7590 10/17/2007

HUMAN GENOME SCIENCES INC.
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
FOSTER, CHRISTINE E	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,669	HE ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-31,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-31,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/17/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment, filed 8/22/07, is acknowledged and has been entered. Claims 21, 23-24, 29, and 34 have been amended. Claims 32-33 have been canceled. Accordingly, claims 21-31 and 34-35 are pending and are under examination.

Terminal Disclaimer

2. The terminal disclaimer filed on 8/9/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,733,981 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Objections/Rejections Withdrawn

3. The objection to the specification is withdrawn in light of the amendments thereto.

4. The rejections of claims 32 and 33 are now moot in light of the Applicant's cancellation of the claims.

5. The rejection of claim 34 under § 112, 2nd paragraph has been withdrawn in light of the amendments thereto.

6. The rejections of claims 21-31 and 34-35 on the grounds of nonstatutory obviousness-type double patenting have been withdrawn in light of the filing of the above-mentioned terminal disclaimer.

7. Any rejections to the claims, that are not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 21-31 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

10. Independent claim 21 has been amended to recite "an antibody or fragment thereof that binds a polypeptide consisting of amino acid residues 1 to 303 of SEQ ID NO:2" in the context of further reciting "detecting binding of polypeptides from said sample to said antibody".

Applicant's reply does not indicate where support could be found in the specification for the newly presented limitations introduced into claim 21. The claims represent a departure from the specification and claims as originally filed for the following reasons.

The specification discloses the 303-residue polypeptide SEQ ID NO:2, which is the putative mature form of the polypeptide ICE-LAP-3 lacking the N-terminal methionine residue (see for example at p. 3, [0019]). The specification also refers to diagnostic assays for detecting altered levels of the ICE-LAP-3 protein (p. 19-20, paragraphs [0095]-[0096]).

The disclosure of assays to detect the single *species* of ICE-LAP-3 (SEQ ID NO:2) using antibodies specific to same does not fully support the instantly claimed invention, which relates not only to detection of the single protein ICE-LAP-3 (SEQ ID NO:2), but to the detection of a

genus of polypeptides that would be bound by antibodies that bind to polypeptides "consisting of amino acid residues 1 to 303 of SEQ ID NO:2". There is no disclosure of assays to detect this genus of polypeptides. In disclosing only assays to detect full-length ICE-LAP-3 (SEQ ID NO:2) using antibodies specific to same, the specification does not provide a written description of the currently claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." MPEP 2163.

It is known that antibodies recognize relatively small regions, termed epitopes, on antigen. See Harlow & Lane (Harlow, E. and Lane, D., Antibodies: A Laboratory Manual (1988) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, pages 23-26, especially at p. 23-24). Because antibodies can recognize relatively small regions of antigens, they can cross-react with similar epitopes on related molecules. However, the presence of similar epitopes does not necessarily imply a functional relationship. See Harlow & Lane at p. 24.

As such, "an antibody or fragment thereof that binds a polypeptide consisting of amino acid residues 1 to 303 of SEQ ID NO:2" would likely contact only a small region out of the entire 303-residue polypeptide that is SEQ ID NO:2. As a result, the polypeptides that are detected by the claimed method in step (b) are not limited to those corresponding to SEQ ID

NO:2 *per se*. Rather, any cross-reacting polypeptide having a similar epitope would be bound by the antibody and detected. This means that Applicant is claiming not only methods of detecting the protein ICE-LAP3 (SEQ ID NO:2), but also methods of detecting any protein that would also cross-react with any anti-ICE-LAP3 antibody.

However, the specification does not support the detection of the genus of such cross-reacting polypeptides claimed because Applicant has described only ICE-LAP3 (SEQ ID NO:2). The specification does not identify any examples of epitopes that would be shared among the polypeptides detected. One skilled in the art would not envisage possession of methods of detecting the genus of polypeptides capable of binding to antibodies that bind to polypeptides "consisting of amino acid residues 1 to 303 of SEQ ID NO:2" because such a genus has not been adequately described.

Applicant has described the genus of polypeptides to be detected only by reference to a functional characteristic, namely, the ability be bound by antibodies that also bind to SEQ ID NO:2. Although presumably this genus of polypeptides to be detected shares a similar antibody epitope in common, no such common epitope is disclosed. Applicant has not described any examples of such epitopes that would be shared by the members of the genus of detected polypeptides. As such, the common structure shared by the genus of polypeptides to be detected is not known. Applicant has not disclosed any partial structure that would be correlated with function (i.e., ability to bind to the antibodies).

Applicant has also not identified what portions of SEQ ID NO:2 would be likely to be antigenic, i.e., what portions or amino acid sequences define antibody epitopes.

Applicant has also not described any *specific* antibodies or fragments thereof that could be used in the claimed detection method, but only mentions antibodies raised against SEQ ID NO:2. No antibodies or fragments thereof are described with any particularity in the specification. No partial structure of the antibodies useful according to the present invention is disclosed. No correlation is disclosed between any such partial structure and function (binding to the claimed polypeptides).

Because neither the common epitope(s) on the polypeptides to be detected, nor the specifics of the antibodies themselves are adequately described in the specification, one skilled in the art cannot envisage possession of the claimed detection methods. Applicant is attempting to describe an unknown by reference to another unknown.

In summary, the specification discloses only detection of ICE-LAP 3 (full-length SEQ ID NO:2) using antibodies specific to same, and does not disclose methods of detecting a genus of polypeptides that have conserved epitopes common to the general of polypeptides that bind to antibodies capable of recognizing polypeptides that consist of SEQ ID NO:2. Applicant has described only detection of SEQ ID NO:2 using antibodies that bind to SEQ ID NO:2. This disclosure does not support the claimed methods of detecting all polypeptides that are bound by antibodies that bind SEQ ID NO:2, since neither the specific antibodies themselves, nor the specific sequence(s) or epitope(s) that would be recognized by such antibodies are adequately described in the specification.

11. Claim 23 as amended recites an immunoassay method "wherein said assay is a competitive-binding assay and wherein said antibody or fragment thereof is bound to a solid support".

The specification mentions at [0096] that competition assays may be employed wherein antibodies specific to ICE-LAP 3 are attached to a solid support. This passage describes a competition assay using **labeled ICE-LAP 3**. In other words, the specification discloses only competitive binding assays where labeled ICE-LAP 3 is competing for binding to the solid support-bound antibody. By contrast, the instant claim does not include the limitation that the assay involves labeled ICE-LAP. As a result, the claim is broader in scope than the competition assay disclosed at [0096] since it would include assays where species other than labeled ICE-LAP 3 compete for binding.

There is no generic disclosure of immunoassay methods wherein antibodies or fragments thereof are bound to a solid support. The introduction into the claims of the limitation of a competitive-binding assay where the antibody or fragment thereof is bound to a solid support, without the accompanying limitation of a competition assay involving labeled ICE-LAP, changes the scope of the disclosure as-filed and therefore represents new matter.

Response to Arguments

12. Applicant's arguments filed 8/9/07 have been fully considered.

13. With respect to the rejections of claims 21-35 under § 112, 1st paragraph as containing new matter, Applicant's arguments (see pages 5-7) have been fully considered but are not persuasive.

With respect to independent claim 21, Applicant argues that the instant amendments to recite "amino acid residues 1 to 303 of SEQ ID NO:2" have obviated the rejection (Reply, the paragraph bridging pages 5-6). However, this amendment does not fully address all grounds of rejection set forth in the previous Office action, which is therefore maintained as set forth above.

Specifically, it is noted that the claims continue to recite methods of detecting not only the single polypeptide ICE-LAP 3 (SEQ ID NO:2) but rather encompass methods of detecting a genus of polypeptides that would cross-react with antibodies that also bind SEQ ID NO:2. It is maintained that such a genus is not adequately described in the specification as filed for reasons of record (see above and the previous Office action at pages 9-13, item 12).

With respect to dependent claim 23, Applicant argues that the amendments to recite competitive-binding assays have obviated the rejection (Reply, page 6, item B). However, the claim still represents a broadening amendment because it claims subject matter disclosed at [0096] but "without the accompanying limitation of a competition assay ***involving labeled ICE-LAP***" as set forth in the previous Office action at pages 13-14, item 13 (emphasis now added). Although the claim has been amended to refer to a competitive-binding assay, it does not recite that the assay employs labeled ICE-LAP 3 as disclosed, and would therefore encompass methods that include other non-disclosed species other than ICE-LAP 3 acting as competitive binding reagents in the assay.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CFoster

Christine Foster
Patent Examiner
Art Unit 1641

LONG V. LE 10/11/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600